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28-DAY DIETARY TOXICITY STUDY IN RODENTS

PRODUCT IDENTIFICATION

Gold Root Extract

STUDY NUMBER

11326

PERFORMING LABORATORY

PRODUCT SAFETY LABS
725 Cranbury Road
East Brunswick, New Jersey 08816

STUDY COMPLETION DATE

May 17, 2002

STUDY DIRECTOR

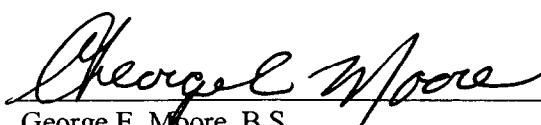
George E. Moore, B.S.

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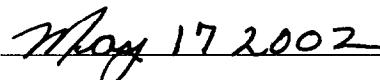
Phytos Inc.
6 Crest Road
San Anselmo, CA 94960

CERTIFICATION

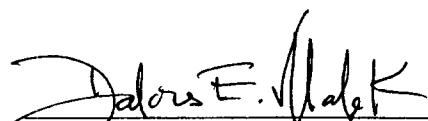
We the undersigned declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study.



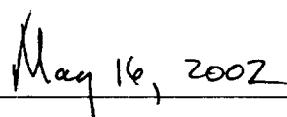
George E. Moore, B.S.
Study Director



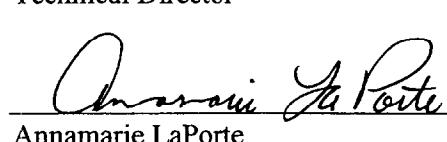
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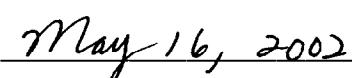
Delores E. Malek, Ph.D., DABT
Technical Director



Date



Annamarie LaPorte
Quality Assurance Auditor



Date



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STUDY INFORMATION

Test Substance: Gold Root Extract

Purity: Unknown

Known Impurities: None considered to be of toxicological significance at this time.

Physical Characteristics: Yellow powder

Stability: Expected to be stable for the duration of testing.

Sponsor: Phytos, Inc
6 Crest Road
San Anselmo, CA 94960

Study Initiated-Completed: November 16, 2001 – (see report cover page)

In-Life Study Initiated-Completed: December 19, 2001 – January 17, 2002

STUDY PERSONNEL

The following individuals were responsible for conduct of the study at Product Safety Labs:

Management: Gary Wnorowski, M.A.

Technical Director: Dolores E. Malek, Ph.D., DABT

Study Director: George E. Moore, B.S.

Primary Technician: Jacek Ochalski, D.V.M.

The following individual was responsible for the clinical pathology evaluations:

Principal Investigator: Barbara A. Litzenberger, B.S., M.T. (ASCP)
Huntingdon Life Sciences
East Millstone, New Jersey 08875

The following individuals were responsible for the histological slide preparation and pathology evaluations:

Histological slides prepared by: Experimental Pathology Laboratories, Inc.
P.O. Box 474
Herndon, VA 20172-0474

Veterinary Pathologist: Kathleen A. Funk, DVM, PhD, Diplomate, ACVP
Experimental Pathology Laboratories, Inc.
P.O. Box 474
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1. SUMMARY

A 28-day dietary toxicity study was conducted in Sprague Dawley Aai: N (SD) BR rats to determine the potential of Gold Root Extract to produce toxicity. Four groups of five rats/sex each were presented with a diet containing 0 (Group 1), 130 (Group 2), 1,300 (Group 3) and 13,000 (Group 4) ppm of the test substance.

Animals were observed daily for clinical signs and mortality. Individual food consumption and body weights were recorded weekly. Blood was sampled from all animals on Day 29 of the study for hematology and clinical chemistry assessments. Gross necropsies were performed on all rats and a limited selection of organs or tissues were taken for histological evaluation. Organs (heart, thymus, adrenals, spleen, liver, kidneys, testes for males and ovaries for females) were weighed from animals sacrificed by design at the end of the study.

The average daily intake of Gold Root Extract in male rats fed dietary concentrations of 0, 130, 1,300 and 13,000 ppm was 0, 11, 115 and 1,144 mg/kg/day, respectively. For the same dietary concentrations, the average daily intake of Gold Root Extract in female rats was 0, 13, 127 and 1,258 mg/kg/day, respectively.

There were no mortalities, clinical signs, clinical pathology, or gross or histopathologic alterations in any test group that were considered to be of toxicological significance. Body weight, body weight gain and nutritional values were also comparable to control for all test groups.

Under the conditions of this study and based on the toxicological endpoints evaluated (which were limited in scope) the no-observed-adverse-effect level (NOAEL) was 13,000 ppm for male and female rats. This level was equivalent to 1,144 and 1,258 mg/kg/day for male and female rats, respectively.

2. OBJECTIVE

The objectives of this study were to determine the oral toxicity and health hazards likely to arise from continuous exposure to Gold Root Extract in the diet for 28 days. The assessment of toxicity was limited to the toxicological endpoints evaluated in this study. A no-observed-adverse-effect level (NOAEL) was sought for each sex based on these endpoints.

3. MATERIALS

This study design is based on OECD Guidelines for Testing of Chemicals, Procedure 407 and Health Effects Test Guidelines, OPPTS 870.3050 for dietary toxicity.

A. Test Substance

The test substance, Gold Root Extract, supplied by the Sponsor was received on September 19, 2001 and identified with PSL Reference Number 010919-8D. The sample was a yellow powder and was stored at room temperature.

B. Test Species

On December 6, 2001, 25 male and 25 female Sprague Dawley Aai: N(SD) BR rats with an assigned birth date of October 30 – November 1, 2001 were received from Ace Animals, Inc., Boyertown, PA.



The rat was selected on the basis of experience with this strain and its suitability with respect to longevity, hardiness, sensitivity, and low incidence of spontaneous disease.

4. METHODS

A. Animal Husbandry

Housing: Animals were housed singly in suspended stainless steel wire mesh cages which conformed to the size recommendations in the most recent *Guide for the Care and Use of Laboratory Animals*, DHEW (NIH). Litter paper placed beneath the cage was changed at least three times per week. The animal room was temperature and humidity controlled, had a 12-hour light/dark cycle and was kept clean and vermin free.

Animal Room Temperature and Relative Humidity Ranges: 18-22°C and 20-47 %

Food: During acclimation, the animals were fed Purina Certified Rodent Chow #5002 *ad libitum*. During the study, the test and control animals received prepared diets using Purina Certified Rodent Meal #5002. The results of analysis for potential feed contaminants are presented in Appendix A.

Water: Filtered tap water was supplied *ad libitum* by an automatic water dispensing system and several animals were given water bottles during the study. A summary of analysis for potential water contaminants is presented in Appendix A.

B. Animal Identification

Cage: Each cage was identified by a cage tag indicating at least the PSL test substance number, group assignment, study number, and identification and sex of the animal.

Animal: Each animal was uniquely identified by a numbered stainless steel ear tag and a sequential animal number. If ear tag was lost during the study the number was written on the tail with an indelible pen.

5. EXPERIMENTAL DESIGN

A. Dose Level Selection

Forty animals (20 male and 20 female) were selected and equally distributed (five/sex/group) into each test group and were presented the test or control substances according to the following design.

Group No.	Dose Test Substance ^a (ppm)	% Test Substance
1 (Control)	0	0
2 (Low)	130	0.013
3 (Intermediate)	1,300	0.13
4 (High)	13,000	1.3

^a based on the assumption of 100% purity



These dose levels were selected to span the range of doses that may be encountered by humans through both normal and exaggerated dietary exposure. A level of 13,000 ppm was selected as the high dose as most regulatory agencies would consider this a limit dose (estimate of 1,000 mg/kg/day), and the lower levels were selected to determine a no-observed-adverse-effect level (NOAEL) based on the toxicological endpoints evaluated.

6. PROCEDURES

A. Diet Preparation and Analyses

The diets were prepared once during the study by Product Safety Labs. All prepared diets were stored at room temperature. For each of the test groups, the test substance was thoroughly mixed by a high-speed mixer into Purina Certified Rodent Meal #5002. Appropriate amounts of the test substance for each dose level and a portion of the meal were mixed in a Hobart A-200 mixer for five minutes.

Retain samples of each test diet were taken from the middle of the mixing bowl immediately after preparation and stored at room temperature for possible future chemical analysis.

B. Selection of Test Groups

After acclimating to the laboratory environment for 13 days, rats were examined for general health and weighed. Only those rats in good health and having a body weight range within $\pm 20\%$ of the mean within a sex were selected for test. Forty rats (20 males; 20 females) were selected for test. They weighed 213-241 grams (males) and 157-178 grams (females) and were approximately seven weeks of age (49 days) at test initiation. The 20 males and 20 females that were used on test were distributed by random assignment (computer generated assignment) into four groups (five/sex/group).

C. Diet Presentation

The test and control diets were presented to each group of rats on Day zero of the study. Additional diet was provided as needed throughout the study to insure *ad libitum* feeding. All animals were exposed to the test and control diets for 28 days.

D. Food Consumption, Food Efficiency and Intake of Gold Root Extract

Individual food consumption was measured and recorded weekly adjusting for spillage. Average food consumption was calculated for each sex/group during each weekly interval and overall (Days 1-28) testing interval. All animals were fasted approximately 20 hours prior to blood collection and necropsy on Day 29. Average food efficiency was also calculated for each sex/group based on body weight gain and food consumption data.

E. Body Weight and Body Weight Gain

Individual body weights were recorded weekly. Average body weight gains were calculated for each sex/group during each weekly interval and overall (Days 0-28) testing interval.



Final body weights were obtained on Day 28. The animals were also weighed immediately prior to sacrifice on Day 29 in order to calculate organ to body weight ratios.

F. Clinical Observations

All animals were observed twice daily for viability. In addition, clinical observations were made and recorded at least once each day. Observations included evaluation of skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity and behavior pattern.

G. Blood Collection

All animals were fasted approximately 20 hours prior to blood collection. Blood samples were collected from all animals from each group via orbital sinus bleeding under isoflurane anesthesia on Day 29. Blood for hematology measurements was collected into tubes containing EDTA anticoagulant. Blood for coagulation assessments was collected into tubes containing sodium citrate anticoagulant. No anticoagulant was used in blood collections for the chemical chemistry measurements.

7. CLINICAL PATHOLOGY EXAMINATION

The following clinical tests were performed on the collected blood samples:

A. Hematology

Hematology parameters were measured from the blood and included, hematocrit, hemoglobin concentration, erythrocyte count, total and differential leukocyte, platelet count. An ADVIA 120 Hematology Analyzer (Bayer Corporation) was used for the analyses. Prothrombin time and activated partial thromboplastin time were also measured using a mechanical clot collection system, STA Compact® (Diagnostica Stago Products).

B. Chemistry

Clinical chemical parameters were measured from the blood serum and included, calcium, chloride, sodium, potassium, phosphorus, fasting glucose, alanine aminotransferase (SGPT), aspartate aminotransferase (SGOT), gamma glutamyl transpeptidase, urea nitrogen, albumin, blood creatinine, total bilirubin, total serum protein, globulin, alkaline phosphatase, total cholesterol and magnesium. A Hitachi 717 (Roche Corporation) automatic analyzer was used for these evaluations.

8. SACRIFICE AND NECROPSY

A. Sacrifice

At terminal sacrifice, all animals were euthanized by exsanguination from the abdominal aorta under isoflurane anesthesia.



B. Necropsy

All animals were subjected to a full gross necropsy, which included examination of the external surface of the body, all orifices and the thoracic and abdominal cavities and their contents for changes in gross appearance. All animals were examined for gross lesions. The heart, thymus, adrenals, spleen, liver, kidneys, testes for males and ovaries for females were weighed wet as soon as possible after dissection to avoid drying. Organ to body weight ratios were calculated on all animals sacrificed by design. The following organs and tissues from all animals were preserved in 10% neutral buffered formalin for possible future histopathological examination: liver, kidneys, stomach, duodenum, jejunum, ileum, cecum, lungs, heart, thymus, adrenals, ovaries or testes and spleen. Additional tissues were preserved if indicated by signs of toxicity.

9. HISTOPATHOLOGY

Histological examinations were performed on liver, kidneys, stomach, small intestines (duodenum, jejunum, ileum), cecum of all animals from the control (Group 1) and high dose (Group 4) groups. In addition, gross lesions (of potential toxicological significance) noted in any test group were evaluated.

Microscopic findings were graded according to the evaluation key shown in Appendix J.

10. STATISTICAL ANALYSES

Mean and standard deviation values were calculated for all quantitative data. Given the small number of animals per group per sex (n=5) no further statistical analysis were conducted.

11. AMENDMENT TO PROTOCOL

8. DATA ANALYSIS

Change From: Mean and standard deviations will be calculated for all quantitative data. Treated groups will be compared to control using an ANOVA. A 95% confidence level will be used to determine statistically significant differences between treated and control groups. Other statistical methods may be used if warranted.

Change To: Mean and standard deviations will be calculated for all quantitative data. Other statistical methods may be used if warranted.

12. QUALITY ASSURANCE

The final report was audited for agreement with the raw data records and for compliance with the study protocol.

13. ARCHIVES

A copy of this report together with the protocol, all raw data, the prepared histological slides with wet and fixed tissues are retained in the Product Safety Labs archives. Raw data is filed in Notebook No. 01-68, pages 1-101.



in concurrent significant decreases in total white blood cell count. Females administered test substance also had decreases in lymphocytes (20% decreased in 13,000 ppm females from control counts) and total white blood cell counts, but the changes were not statistically significant. With the exception of one 13,000 ppm female rat the values for lymphocyte count and total white blood cell count for both males and females fell within the range for historical control data (See end Appendix I, Attachment I). Given this, and in the absence of a definitive dose response relationship, these decreases were considered not to be of clinical significance.

There were minimal, but statistically significant ($p < 0.05$) decreases in monocytes among 1,300 and 13,000 ppm females and in basophils among 1,300 and 13,000 ppm males. Monocytes were decreased among males receiving test substance in a dose dependent, but not statistically significant manner. Large unstained cells were decreased in 1,300 ($p < 0.01$) and 13,000 ($p < 0.05$) males compared to controls. The minor shifts in all of these cell populations were not considered clinically relevant.

Hematocrit was significantly ($p < 0.05$) decreased only among 130 ppm males and not among 1,300 or 13,000 ppm males, making a test substance effect doubtful. All hematocrit values were within the range of historical control data (See end Appendix I, Attachment I).

Clinical Chemistry

Slight but statistically significant ($p < 0.01$) increase in serum sodium was present among 13,000 ppm males and females compared to controls. Serum chloride was significantly increased in 1,300 ppm ($p < 0.05$) and 13,000 ppm ($p < 0.01$) males and in 13,000 ppm females ($p < 0.05$). These apparent test substance effects on electrolyte levels were of minimal magnitude and clinical significance. All of the individual and mean values fell within ranges of respective historical control parameters (See end Appendix I, Attachment I).

Calcium and phosphorus were significantly ($p < 0.01$) increased among 1,300 ppm females and not among 13,000 ppm females, making a test substance effect doubtful.

Total protein ($p < 0.01$) and albumin ($p < 0.05$) were increased among 13,000 ppm males. All of the individual and mean values fell within ranges of respective historical control parameters (See end Appendix I, Attachment I).

I. Histopathology (Appendix J)

There were no lesions observed in male and female rats at 13,000 ppm (Group 4) when compared to control (Group 1) that were considered attributable to the dietary administration of Gold Root. All of the alterations observed (such as inflammation and vacuolation of the liver, and evidence of mineralization in the kidney) were graded minimal to slight/mild and are considered common background findings in rats of this age and strain.

15. CONCLUSION

Under the conditions of this study and based on the toxicological endpoints evaluated to date (which were limited in scope), the NOAEL for Gold Root Extract was 13,000 ppm for male (1,144 mg/kg/day) and female (1,258 mg/kg/day) rats.



14. RESULTS AND DISCUSSION

A. Diet Analyses

No analysis of diet was performed. Test substance in diets were assumed to be homogeneously distributed and at expected concentrations. Thus, test animals were similarly assumed to have received targeted levels (mg/kg/day) of Gold Root Extract throughout the study.

B. Mortality

There were no mortalities throughout the study.

C. Clinical Observations (Appendix B)

All animals appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior.

D. Average Body Weight and Body Weight Gain (Tables 1 and 2, Appendices C and D)

Average overall (0-28 Days) body weight and body weight gain for all groups of male and female rats were comparable to control values.

E. Gross Necropsy (Appendix E)

No gross abnormalities were noted for the animals when necropsied at the conclusion of the study.

F. Organ Weights and Organ to Body Weight Ratios (Tables 7 and 8, Appendices F and G)

Organ weights (absolute) and organ to body weight ratios (relative) for each group of male and female rats were compared to control values. There were no differences in absolute and relative organ weights that were considered attributable to the dietary administration of Gold Root Extract.

G. Average Daily Food Consumption, Food Efficiency and Intake of Gold Root Extract (Tables 3 to 6, Appendix H)

Average overall (0-28 Days) daily food consumption and food efficiency for all groups of male and female rats were comparable to control values. The average daily intake of Gold Root Extract in male rats fed dietary concentrations of 0, 130, 1,300 and 13,000 ppm was 0, 11, 115 and 1,144 mg/kg/day, respectively. For the same dietary concentrations the average daily intake of Gold Root Extract in female rats was 0, 13, 127 and 1,258 mg/kg/day.

H. Clinical Pathology Examination (Tables 9 and 10, Appendix I)

Hematology

Male rats had statistically significant ($p < 0.01$) decreases in lymphocytes at all dosage levels (130, 1,300 and 13,000 ppm) of test substance compared to control males. The mean lymphocyte count among 13,000 ppm males was decreased 33% from controls. The decreases in lymphocytes resulted

TABLE 1: AVERAGE WEEKLY BODY WEIGHT (grams)
MALES

GROUP		1	2	3	4
DOSE LEVEL (PPM)		0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP		5	5	5	5
WEEK					
0	Avg.	227.8	228.6	228.2	229.6
	SD	10.6	7.8	10.6	8.8
1	Avg.	284.6	280.8	259.8	274.2
	SD	8.6	9.8	18.3	17.4
2	Avg.	329.0	323.0	323.6	323.8
	SD	11.3	12.5	13.0	18.3
3	Avg.	353.0	350.8	351.8	350.2
	SD	12.2	16.0	18.1	16.5
4	Avg.	379.4	376.0	378.6	375.4
	SD	9.3	19.6	21.5	15.2
1-28	Avg.	314.8	311.8	308.4	310.6
	SD	8.7	12.8	13.0	14.1

FEMALES

GROUP		1	2	3	4
DOSE LEVEL (PPM)		0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP		5	5	5	5
WEEK					
0	Avg.	167.4	169.0	168.6	167.0
	SD	7.0	6.3	8.0	7.7
1	Avg.	185.8	193.0	187.2	191.4
	SD	6.5	10.9	4.2	10.4
2	Avg.	206.6	217.4	217.8	207.6
	SD	10.0	10.8	7.8	11.6
3	Avg.	220.0	237.6	224.2	224.8
	SD	12.1	6.4	5.1	12.1
4	Avg.	236.4	251.0	246.2	244.4
	SD	17.2	13.9	5.2	15.7
1-28	Avg.	203.2	213.6	208.8	207.0
	SD	10.3	8.7	3.7	10.8



TABLE 2: AVERAGE WEEKLY BODY WEIGHT GAIN (grams)

MALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP	5	5	5	5	
WEEK					
1	Avg.	56.8	52.2	31.4	44.6
	SD	5.1	4.3	19.1	11.8
2	Avg.	44.4	42.2	63.8	49.6
	SD	7.1	4.4	20.1	12.7
3	Avg.	24.0	27.8	28.2	26.4
	SD	5.0	4.2	7.9	3.8
4	Avg.	26.4	25.2	26.8	25.2
	SD	4.1	5.7	4.1	1.8
1-28	Avg.	37.9	36.9	37.6	36.5
	SD	3.3	3.4	3.3	2.5

FEMALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP	5	5	5	5	
WEEK					
1	Avg.	18.4	24.0	18.6	24.4
	SD	1.8	7.3	6.8	4.4
2	Avg.	20.8	24.4	30.6	16.2
	SD	4.3	8.0	5.3	3.5
3	Avg.	13.4	20.2	6.4	17.2
	SD	3.8	7.1	7.7	2.3
4	Avg.	16.4	13.4	22.0	19.6
	SD	6.8	10.9	6.5	9.8
1-28	Avg.	17.3	20.5	19.4	19.4
	SD	2.9	2.5	2.0	2.5



TABLE 3: AVERAGE DAILY FOOD CONSUMPTION¹ (grams)

MALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP	5	5	5	5	
WEEK					
1	Avg.	27.6	26.0	24.0	25.7
	SD	0.8	1.2	1.0	1.9
2	Avg.	28.7	26.8	29.3	28.0
	SD	1.6	1.1	1.8	1.7
3	Avg.	27.4	26.2	26.9	27.4
	SD	1.4	1.1	1.4	1.2
4	Avg.	28.9	27.2	28.0	27.3
	SD	1.8	1.8	1.2	0.7
1-28	Avg.	28.2	26.5	27.0	27.1
	SD	1.3	1.3	0.9	1.1

FEMALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP	5	5	5	5	
WEEK					
1	Avg.	18.8	19.7	19.1	19.8
	SD	0.7	1.6	0.6	1.6
2	Avg.	19.0	20.7	20.2	19.7
	SD	1.6	1.0	1.3	1.4
3	Avg.	19.3	20.0	18.1	19.4
	SD	1.8	1.2	1.4	1.4
4	Avg.	21.1	21.7	20.5	20.7
	SD	1.5	1.9	1.1	1.8
1-28	Avg.	19.6	20.5	19.5	19.9
	SD	1.2	0.8	0.7	1.3

¹ Estimated values based on weekly individual animal food consumption measurements (See Table 4).



TABLE 4: AVERAGE WEEKLY FOOD CONSUMPTION (grams)

MALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP	5	5	5	5	
WEEK					
1	Avg.	193.4	181.7	168.0	180.1
	SD	5.4	8.7	7.1	13.0
2	Avg.	200.8	187.8	205.0	195.7
	SD	10.9	8.0	12.8	11.8
3	Avg.	191.9	183.2	188.0	191.6
	SD	9.7	7.5	9.6	8.1
4	Avg.	202.4	190.1	196.1	191.1
	SD	12.6	12.7	8.3	4.9
1-28	Avg.	197.1	185.7	189.3	189.6
	SD	9.1	9.0	6.2	7.8

FEMALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP	5	5	5	5	
WEEK					
1	Avg.	131.7	137.8	134.0	138.4
	SD	4.9	11.5	4.5	10.9
2	Avg.	133.1	145.2	141.4	137.6
	SD	11.1	6.8	8.9	9.9
3	Avg.	135.1	140.0	127.0	136.1
	SD	12.7	8.6	10.0	9.8
4	Avg.	147.8	152.1	143.3	144.9
	SD	10.8	13.5	7.4	12.5
1-28	Avg.	136.9	143.8	136.4	139.2
	SD	8.6	5.8	5.1	9.1



TABLE 5: AVERAGE WEEKLY FOOD EFFICIENCY¹

MALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP	5	5	5	5
WEEK				
1	Avg.	0.29	0.29	0.19
	SD	0.03	0.02	0.11
2	Avg.	0.22	0.22	0.31
	SD	0.04	0.02	0.08
3	Avg.	0.13	0.15	0.15
	SD	0.03	0.02	0.04
4	Avg.	0.13	0.13	0.14
	SD	0.02	0.03	0.02
1-28	Avg.	0.19	0.20	0.20
	SD	0.02	0.01	0.01

FEMALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP	5	5	5	5
WEEK				
1	Avg.	0.14	0.17	0.14
	SD	0.01	0.04	0.05
2	Avg.	0.16	0.17	0.22
	SD	0.02	0.05	0.03
3	Avg.	0.10	0.14	0.05
	SD	0.02	0.05	0.06
4	Avg.	0.11	0.09	0.15
	SD	0.04	0.06	0.04
1-28	Avg.	0.13	0.14	0.14
	SD	0.01	0.01	0.01

¹ Food efficiency = $\frac{\text{Weekly Body Weight Gain}}{\text{Weekly Food Consumption}}$



TABLE 6: AVERAGE DAILY INTAKE OF GOLD ROOT EXTRACT¹ (mg/kg/day)

MALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP	5	5	5	5
WEEK				
1	0	13	128	1,328
2	0	12	131	1,216
3	0	10	103	1,056
4	0	10	100	978
1-28 ²	0	11	115	1,144

FEMALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP	5	5	5	5
WEEK				
1	0	14	140	1,435
2	0	13	130	1,281
3	0	11	115	1,169
4	0	12	123	1,147
1-28 ²	0	13	127	1,258

1

Avg. Daily Intake of Gold Root Extract = $\frac{(\text{Total Avg. Food Consumption for Test Period (mg)})(\text{Dose Level (PPM)})}{\text{Avg. Body Weight for Test Period}}$ /Number of Days in Test Period

² 1-28 day values are the average value of all weekly values.



TABLE 7: AVERAGE ORGAN WEIGHTS (grams)

MALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Organ				
Thymus	Avg.	0.60	0.61	0.67
	SD	0.085	0.118	0.059
Adrenal (paired)	Avg.	0.060	0.072	0.069 ²
	SD	0.008	0.012	0.016
Heart	Avg.	1.35	1.32	1.29
	SD	0.088	0.142	0.090
Spleen	Avg.	0.93	0.82	0.84
	SD	0.150	0.062	0.170
Liver	Avg.	10.91	10.60	10.88
	SD	0.284	0.836	0.361
Testes (paired)	Avg.	3.240	3.140	3.260
	SD	0.282	0.183	0.352
Kidney (paired)	Avg.	2.88	2.86	2.82
	SD	0.176	0.270	0.310

¹ Indicates the total number of rats that provided organs, only animals sacrificed by design are included.

² Average Adrenal weight for four animals in Group 3.

TABLE 7 (cont.): AVERAGE ORGAN WEIGHTS (grams)
FEMALES

GROUP		1	2	3	4
DOSE LEVEL (PPM)		0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹		5	5	5	5
Organ					
Thymus	Avg.	0.46	0.54	0.55	0.46
	SD	0.109	0.196	0.081	0.086
Adrenal (paired)	Avg.	0.086	0.089	0.087	0.078
	SD	0.015	0.012	0.014	0.007
Heart	Avg.	0.93	0.96	0.97	0.91
	SD	0.099	0.041	0.042	0.109
Spleen	Avg.	0.63	0.66	0.59	0.59
	SD	0.166	0.067	0.093	0.088
Liver	Avg.	6.81	7.36	7.36	7.06
	SD	0.879	0.618	0.571	0.982
Ovaries (paired)	Avg.	0.108	0.115	0.112	0.094
	SD	0.010	0.021	0.020	0.015
Kidney (paired)	Avg.	1.82	1.96	1.87	1.85
	SD	0.103	0.133	0.061	0.208

¹ Indicates the total number of rats that provided organs, only animals sacrificed by design are included.



TABLE 8: AVERAGE ORGAN TO BODY WEIGHT RATIOS

MALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5	
Organ					
Thymus	Avg.	1.76	1.79	1.96	1.78
	SD	0.24	0.29	0.21	0.46
Adrenal (paired)	Avg.	0.175	0.213	0.204	0.189
	SD	0.021	0.039	0.047	0.018
Heart	Avg.	3.96	3.90	3.79	3.66
	SD	0.231	0.357	0.289	0.181
Spleen	Avg.	2.74	2.43	2.47	2.47
	SD	0.483	0.247	0.541	0.402
Liver	Avg.	32.1	31.2	32.0	31.0
	SD	1.08	2.10	1.37	1.38
Testes (paired)	Avg.	9.54	9.28	9.55	9.91
	SD	0.895	0.869	0.593	0.142
Kidney (paired)	Avg.	8.46	8.44	8.28	8.11
	SD	0.538	0.713	0.658	0.508

¹ Indicates the total number of rats used for organ to body weight ratios; only animals sacrificed by design are included.

TABLE 8 (cont.): AVERAGE ORGAN TO BODY WEIGHT RATIOS
FEMALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP¹	5	5	5	5
Organ				
Thymus	Avg.	2.19	2.45	2.55
	SD	0.43	0.75	0.39
Adrenal (paired)	Avg.	0.407	0.408	0.408
	SD	0.046	0.070	0.060
Heart	Avg.	4.44	4.35	4.53
	SD	0.316	0.276	0.136
Spleen	Avg.	2.97	2.98	2.75
	SD	0.585	0.235	0.381
Liver	Avg.	32.4	33.4	34.4
	SD	1.76	2.09	2.48
Ovaries (paired)	Avg.	0.516	0.526	0.526
	SD	0.065	0.112	0.101
Kidney (paired)	Avg.	8.71	8.89	8.75
	SD	0.282	0.266	0.444

¹ Indicates the total number of rats used for organ to body weight ratios; only animals sacrificed by design are included.

TABLE 9: AVERAGE HEMATOLOGY VALUES
MALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Parameter (units)				
Hemoglobin Conc. (g/dL)	Avg.	17.0	16.1	16.8
	SD	0.5	1.1	0.5
Hematocrit (%)	Avg.	49.8	46.8*	50.0
	SD	1.0	3.1	1.3
Erythrocyte Ct. (10 ⁶ /µL)	Avg.	9.10	8.73	9.23
	SD	0.46	0.65	0.26
Platelet Count (10 ³ /µL)	Avg.	1003	872	718
	SD	70.0	177.5	313.8
Total Leukocyte Ct. (10 ³ /µL)	Avg.	11.21	8.50*	7.76**
	SD	1.03	1.79	0.75
Absolute Neutrophils (10 ³ /µL)	Avg.	0.70	1.05	0.66
	SD	0.19	0.53	0.21
Absolute Lymphocytes (10 ³ /µL)	Avg.	9.95	6.90**	6.57**
	SD	1.08	1.57	1.06

* Significant difference ($p < 0.05$) from control animals by Dunnett Multiple Comparison Test.

** Significant difference ($p < 0.01$) from control animals by Dunnett Multiple Comparison Test.

¹ Indicates the total number of rats from which blood was collected and used to determine average hematology values.

TABLE 9 (cont.): AVERAGE HEMATOLOGY VALUES
MALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Parameter (units)				
Absolute Monocytes ($10^3/\mu\text{L}$)	Avg.	0.29	0.23	0.18
	SD	0.05	0.09	0.07
Absolute Eosinophils ($10^3/\mu\text{L}$)	Avg.	0.15	0.23	0.23
	SD	0.06	0.15	0.31
Absolute Basophils ($10^3/\mu\text{L}$)	Avg.	0.06	0.04	0.02*
	SD	0.01	0.01	0.02
Absolute Large Unstained Cells ($10^3/\mu\text{L}$)	Avg.	0.07	0.05	0.02**
	SD	0.02	0.02	0.02
Prothrombin Time (sec)	Avg.	12.6	12.2	12.0
	SD	0.3	0.3	0.6
Activated Partial Thromboplastin Time (sec)	Avg.	19.9	19.0	18.7
	SD	1.7	1.4	0.8
				1.9

* Significant difference ($p < 0.05$) from control animals by Dunnett Multiple Comparison Test.

** Significant difference ($p < 0.01$) from control animals by Dunnett Multiple Comparison Test.

¹ Indicates the total number of rats from which blood was collected and used to determine average hematology values.



TABLE 9 (cont.): AVERAGE HEMATOLOGY VALUES

FEMALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Parameter (units)				
Hemoglobin Conc. (g/dL)	Avg.	15.7	15.5	16.3
	SD	0.9	1.6	0.5
Hematocrit (%)	Avg.	44.9	44.4	46.7
	SD	3.0	4.8	1.6
Erythrocyte Ct. ($10^6/\mu\text{L}$)	Avg.	8.31	8.17	8.67
	SD	0.43	0.92	0.33
Platelet Count ($10^3/\mu\text{L}$)	Avg.	1213	990	1091
	SD	117.0	290.8	387.8
Total Leukocyte Ct. ($10^3/\mu\text{L}$)	Avg.	6.71	5.51	5.48
	SD	1.75	1.67	0.71
Absolute Neutrophils ($10^3/\mu\text{L}$)	Avg.	0.66	0.51	0.43
	SD	0.33	0.16	0.13
Absolute Lymphocytes ($10^3/\mu\text{L}$)	Avg.	5.72	4.71	4.82
	SD	1.63	1.55	0.61

¹ Indicates the total number of rats from which blood was collected and used to determine average hematology values.



TABLE 9 (cont.): AVERAGE HEMATOLOGY VALUES

FEMALES

GROUP	1	2	3	4	
DOSE LEVEL (PPM)	0	130	1,300	13,000	
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5	
Parameter (units)					
Absolute Monocytes (10 ³ /µL)	Avg.	0.16	0.12	0.08*	0.08*
	SD	0.03	0.04	0.03	0.06
Absolute Eosinophils (10 ³ /µL)	Avg.	0.11	0.10	0.10	0.14
	SD	0.05	0.07	0.05	0.13
Absolute Basophils (10 ³ /µL)	Avg.	0.02	0.02	0.01	0.01
	SD	0.01	0.01	0.01	0.01
Absolute Large Unstained Cells (10 ³ /µL)	Avg.	0.03	0.03	0.02	0.02
	SD	0.02	0.03	0.01	0.01
Prothrombin Time (sec)	Avg.	11.8	11.6	11.6	12.4 ²
	SD	0.1	0.3	0.3	0.9
Activated Partial Thromboplastin Time (sec)	Avg.	16.1	16.7	15.3 ³	18.2 ²
	SD	1.1	0.6	0.9	2.9

* Significant difference ($p < 0.05$) from control animals by Dunnett Multiple Comparison Test.

¹ Indicates the total number of rats from which blood was collected and used to determine average hematology values.

² Average Prothrombin and Activated Partial Thromboplastin values for four animals in Group 4.

³ Average Activated Partial Thromboplastin value for four animals in Group 3.



TABLE 10: AVERAGE BLOOD CHEMISTRY VALUES

MALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Parameter (units)				
Aspartate Aminotransferase SGOT (IU/L)	Avg.	166	192	192
	SD	28.1	39.1	21.9
Alanine Aminotransferase SGPT (IU/L)	Avg.	44	46	50
	SD	4.0	3.8	11.2
Alkaline Phosphatase (IU/L)	Avg.	160	142	178
	SD	32.0	20.1	48.2
Blood Urea Nitrogen (mg/dL)	Avg.	14.0	13.8	13.3
	SD	2.0	2.1	2.7
Creatinine (mg/dL)	Avg.	0.3	0.3	0.3
	SD	0.1	0.0	0.1
Fasting Glucose (mg/dL)	Avg.	114	110	99
	SD	14.1	23.3	8.7
Cholesterol (mg/dL)	Avg.	83	73	74
	SD	18.9	14.2	6.0
Total Protein (g/dL)	Avg.	6.3	6.3	6.4
	SD	0.2	0.2	0.1
Albumin (g/dL)	Avg.	3.9	4.1	4.1
	SD	0.2	0.2	0.2
Globulin (g/dL)	Avg.	2.3	2.2	2.3
	SD	0.2	0.1	0.2
Total Bilirubin (mg/dL)	Avg.	0.07	0.07	0.06
	SD	0.03	0.01	0.02

* Significant difference ($p < 0.05$) from control animals by Dunnett Multiple Comparison Test.** Significant difference ($p < 0.01$) from control animals by Dunnett Multiple Comparison Test.

¹ Indicates the total number of rats from which blood was collected and used to determine average blood chemistry values.



TABLE 10 (cont.): AVERAGE BLOOD CHEMISTRY VALUES

MALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Parameter (units)				
Sodium (mEq/L)	Avg.	147	148	148
	SD	0.5	1.0	0.9
Potassium (mEq/L)	Avg.	4.9	4.9	5.1
	SD	0.1	0.3	0.2
Chloride (mEq/L)	Avg.	104	105	106*
	SD	1.1	0.5	1.6
Calcium (mg/dL)	Avg.	10.3	10.2	10.4
	SD	0.2	0.2	0.4
Inorganic Phosphorus (mg/dL)	Avg.	7.1	7.2	7.3
	SD	0.3	0.5	0.3
Magnesium (mg/dL)	Avg.	1.82	1.85	1.82
	SD	0.12	0.17	0.07
Gamma-Glutamyl Transferase (IU/L)	Avg.	0	0	0
	SD	0.0	0.0	0.0

* Significant difference ($p < 0.05$) from control animals by Dunnett Multiple Comparison Test.

** Significant difference ($p < 0.01$) from control animals by Dunnett Multiple Comparison Test.

¹ Indicates the total number of rats from which blood was collected and used to determine average blood chemistry values.

TABLE 10 (cont.): AVERAGE BLOOD CHEMISTRY VALUES
FEMALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Parameter (units)				
Aspartate Aminotransferase SGOT (IU/L)	Avg.	168	157	184
	SD	13.9	26.3	27.9
Alanine Aminotransferase SGPT (IU/L)	Avg.	41	34	34
	SD	7.4	4.4	1.5
Alkaline Phosphatase (IU/L)	Avg.	127	128	107
	SD	23.3	27.9	25.3
Blood Urea Nitrogen (mg/dL)	Avg.	14.4	15.7	15.1
	SD	2.1	1.3	0.7
Creatinine (mg/dL)	Avg.	0.2	0.3	0.3
	SD	0.1	0.1	0.0
Fasting Glucose (mg/dL)	Avg.	100	100	101
	SD	8.9	14.7	13.9
Cholesterol (mg/dL)	Avg.	71	69	87
	SD	10.3	10.2	8.3
Total Protein (g/dL)	Avg.	6.2	6.2	6.3
	SD	0.2	0.1	0.1
Albumin (g/dL)	Avg.	4.3	4.2	4.3
	SD	0.2	0.2	0.1
Globulin (g/dL)	Avg.	1.9	2.0	2.0
	SD	0.2	0.2	0.1
Total Bilirubin (mg/dL)	Avg.	0.10	0.09	0.10
	SD	0.03	0.02	0.02

¹ Indicates the total number of rats from which blood was collected and used to determine average blood chemistry values.



TABLE 10 (cont.): AVERAGE BLOOD CHEMISTRY VALUES

FEMALES

GROUP	1	2	3	4
DOSE LEVEL (PPM)	0	130	1,300	13,000
NUMBER OF ANIMALS IN GROUP ¹	5	5	5	5
Parameter (units)				
Sodium (mEq/L)	Avg.	146	146	146
	SD	0.9	1.1	1.2
Potassium (mEq/L)	Avg.	4.9	4.7	5.1
	SD	0.3	0.3	0.3
Chloride (mEq/L)	Avg.	105	106	105
	SD	1.9	1.4	1.1
Calcium (mg/dL)	Avg.	10.2	10.3	10.6**
	SD	0.2	0.2	0.1
Inorganic Phosphorus (mg/dL)	Avg.	6.3	6.8	7.5**
	SD	0.5	0.5	0.7
Magnesium (mg/dL)	Avg.	1.97	1.98	2.07
	SD	0.05	0.07	0.10
Gamma-Glutamyl Transferase (IU/L)	Avg.	0	0	0
	SD	0.0	0.0	0.4

* Significant difference ($p < 0.05$) from control animals by Dunnett Multiple Comparison Test.

** Significant difference ($p < 0.01$) from control animals by Dunnett Multiple Comparison Test.

¹ Indicates the total number of rats from which blood was collected and used to determine average blood chemistry values.

APPENDIX A

PRODUCT IDENTIFICATION

Gold Root Extract

FOOD AND WATER ANALYSES



APPENDIX A

FEED

PURINA CERTIFIED RODENT MEAL #5002, LOT CODE OCT 10 01 1B

<u>ASSAY</u>	<u>ANALYSIS</u>
Protein (N x 6.25)	21.0%
Fat (Acid Hydro.)	5.58%
Fiber (Crude)	4.45%
Arsenic	0.200 ppm
Cadmium	0.059 ppm
Calcium	0.913%
Lead	0.174%
Mercury	< 0.025 ppm
Phosphorus	0.602%
Selenium	0.295 ppm

Animal feed analysis routinely performed for presence of chlorinated insecticides:

Aldrin	< 0.02 ppm	HCB	< 0.02 ppm
BHC: alpha	< 0.02 ppm	Heptachlor	< 0.02 ppm
beta	< 0.02 ppm	Heptachlor	
delta	< 0.02 ppm	Epoxide	< 0.02 ppm
Chlordane	< 0.02 ppm	Lindane	< 0.02 ppm
DDE	< 0.02 ppm	Methoxychlor	< 0.02 ppm
DDT	< 0.02 ppm	Mirex	< 0.02 ppm
Dieldrin	< 0.02 ppm	PCB	< 0.15 ppm
Endrin	< 0.02 ppm		

for the presence of organophosphate insecticides:

Diazinon	< 0.02 ppm	Parathion	< 0.02 ppm
Disulfoton	< 0.02 ppm	Thimet	< 0.02 ppm
Ethion	< 0.02 ppm	Thiodan	< 0.02 ppm
Malathion	< 0.02 ppm	Triithion	< 0.02 ppm
Methyl Parathion	< 0.02 ppm		
Aflatoxin	Total: < 5 ppb		

LABORATORY: PMI FEEDS, INC.
1401 S. Hanley Road
St. Louis, MO 63144

APPENDIX A (cont.)

WATER

Water analysis performed on January 3, 2002 for NJDEPE Safe Drinking Water Act parameters and percent fluoride content.

LABORATORY: NEW JERSEY LABORATORIES
 NJDEPE #12660
 A.A. Labs Division
 222 Easton Avenue
 New Brunswick, NJ 08901

SAMPLE NUMBER: D804

Results of water analysis for possible contaminants: Acceptable; none detected or within regulatory standards.

APPENDIX B

PRODUCT IDENTIFICATION

Gold Root Extract

INDIVIDUAL IN-LIFE OBSERVATIONS

APPENDIX B

INDIVIDUAL IN-LIFE ANIMAL OBSERVATIONS

<u>Animal Number</u>	<u>Finding</u>	<u>Day of Occurrence</u>
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GROUP 1 – (0 ppm)

MALES

7957-7961	Active and healthy	Throughout study
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FEMALES

7962-7966	Active and healthy	Throughout study
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GROUP 2 – (130 ppm)

MALES

7967-7971	Active and healthy	Throughout study
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FEMALES

7972-7976	Active and healthy	Throughout study
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GROUP 3 –(1,300 ppm)

MALES

7977-7981	Active and healthy	Throughout study
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FEMALES

7982-7986	Active and healthy	Throughout study
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GROUP 4 - (13,000 ppm)

MALES

7987-7991	Active and healthy	Throughout study
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FEMALES

7992-7996	Active and healthy	Throughout study
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APPENDIX C

PRODUCT IDENTIFICATION

Gold Root Extract

INDIVIDUAL BODY WEIGHTS



APPENDIX C

BODY WEIGHT (grams)

GROUP 1 - (0 ppm)

MALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7957	224	288	342	363	388
7958	240	290	325	342	369
7959	226	284	332	358	380
7960	236	291	334	364	389
7961	213	270	312	338	371
Average	227.8	284.6	329.0	353.0	379.4
SD	10.6	8.6	11.3	12.2	9.3

FEMALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7962	163	184	201	219	230
7963	160	178	198	209	225
7964	170	186	209	220	230
7965	178	196	223	240	267
7966	166	185	202	212	230
Average	167.4	185.8	206.6	220.0	236.4
SD	7.0	6.5	10.0	12.1	17.2



APPENDIX C (cont.)

BODY WEIGHT (grams)

GROUP 2 - (130 ppm)

MALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7967	233	291	330	360	395
7968	221	271	312	341	362
7969	224	279	323	350	373
7970	225	272	310	331	353
7971	240	291	340	372	397
Average	228.6	280.8	323.0	350.8	376.0
SD	7.8	9.8	12.5	16.0	19.6

FEMALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7972	173	206	223	243	273
7973	177	195	232	241	256
7974	165	184	208	228	243
7975	169	200	218	242	245
7976	161	180	206	234	238
Average	169.0	193.0	217.4	237.6	251.0
SD	6.3	10.9	10.8	6.4	13.9

APPENDIX C (cont.)
BODY WEIGHT (grams)
GROUP 3 - (1,300 ppm)
MALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7977	241	248	336	370	400
7978	213	240	306	330	351
7979	232	255	333	371	401
7980	223	270	314	341	370
7981	232	286	329	347	371
Average	228.2	259.8	323.6	351.8	378.6
SD	10.6	18.3	13.0	18.1	21.5

FEMALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7982	164	188	222	224	239
7983	158	183	218	222	249
7984	176	194	228	230	245
7985	177	185	208	228	253
7986	168	186	213	217	245
Average	168.6	187.2	217.8	224.2	246.2
SD	8.0	4.2	7.8	5.1	5.2



APPENDIX C (cont.)

BODY WEIGHT (grams)

GROUP 4 - (13,000 ppm)

MALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7987	229	262	334	364	388
7988	237	293	338	361	385
7989	221	252	293	324	352
7990	240	289	333	358	384
7991	221	275	321	344	368
Average	229.6	274.2	323.8	350.2	375.4
SD	8.8	17.4	18.3	16.5	15.2

FEMALES

Animal #	Day 0	Day 7	Day 14	Day 21	Day 28
7992	165	192	204	224	236
7993	178	206	224	240	261
7994	165	182	202	220	256
7995	157	181	194	208	222
7996	170	196	214	232	247
Average	167.0	191.4	207.6	224.8	244.4
SD	7.7	10.4	11.6	12.1	15.7

3

APPENDIX D

PRODUCT IDENTIFICATION

Gold Root Extract

INDIVIDUAL BODY WEIGHT GAIN

APPENDIX D

INDIVIDUAL BODY WEIGHT GAIN (grams) – GROUP 1

MALES

Animal #	Week			
	1	2	3	4
7957	64.0	54.0	21.0	25.0
7958	50.0	35.0	17.0	27.0
7959	58.0	48.0	26.0	22.0
7960	55.0	43.0	30.0	25.0
7961	57.0	42.0	26.0	33.0
Avg.	56.8	44.4	24.0	26.4
SD	5.1	7.1	5.0	4.1

FEMALES

Animal #	Week			
	1	2	3	4
7962	21.0	17.0	18.0	11.0
7963	18.0	20.0	11.0	16.0
7964	16.0	23.0	11.0	10.0
7965	18.0	27.0	17.0	27.0
7966	19.0	17.0	10.0	18.0
Avg.	18.4	20.8	13.4	16.4
SD	1.8	4.3	3.8	6.8



APPENDIX D (cont.)
INDIVIDUAL BODY WEIGHT GAIN (grams) – GROUP 2

MALES

Animal #	Week			
	1	2	3	4
7967	58.0	39.0	30.0	35.0
7968	50.0	41.0	29.0	21.0
7969	55.0	44.0	27.0	23.0
7970	47.0	38.0	21.0	22.0
7971	51.0	49.0	32.0	25.0
Avg.	52.2	42.2	27.8	25.2
SD	4.3	4.4	4.2	5.7

FEMALES

Animal #	Week			
	1	2	3	4
7972	33.0	17.0	20.0	30.0
7973	18.0	37.0	9.0	15.0
7974	19.0	24.0	20.0	15.0
7975	31.0	18.0	24.0	3.0
7976	19.0	26.0	28.0	4.0
Avg.	24.0	24.4	20.2	13.4
SD	7.3	8.0	7.1	10.9

APPENDIX D (cont.)
INDIVIDUAL BODY WEIGHT GAIN (grams) – GROUP 3

MALES

Animal #	Week			
	1	2	3	4
7977	7.0	88.0	34.0	30.0
7978	27.0	66.0	24.0	21.0
7979	23.0	78.0	38.0	30.0
7980	47.0	44.0	27.0	29.0
7981	54.0	43.0	18.0	24.0
Avg.	31.4	63.8	28.2	26.8
SD	19.1	20.1	7.9	4.1

FEMALES

Animal #	Week			
	1	2	3	4
7982	24.0	34.0	2.0	15.0
7983	25.0	35.0	4.0	27.0
7984	18.0	34.0	2.0	15.0
7985	8.0	23.0	20.0	25.0
7986	18.0	27.0	4.0	28.0
Avg.	18.6	30.6	6.4	22.0
SD	6.8	5.3	7.7	6.5

APPENDIX D (cont.)
INDIVIDUAL BODY WEIGHT GAIN (grams) – GROUP 4

MALES

Animal #	Week			
	1	2	3	4
7987	33.0	72.0	30.0	24.0
7988	56.0	45.0	23.0	24.0
7989	31.0	41.0	31.0	28.0
7990	49.0	44.0	25.0	26.0
7991	54.0	46.0	23.0	24.0
Avg.	44.6	49.6	26.4	25.2
SD	11.8	12.7	3.8	1.8

FEMALES

Animal #	Week			
	1	2	3	4
7992	27.0	12.0	20.0	12.0
7993	28.0	18.0	16.0	21.0
7994	17.0	20.0	18.0	36.0
7995	24.0	13.0	14.0	14.0
7996	26.0	18.0	18.0	15.0
Avg.	24.4	16.2	17.2	19.6
SD	4.4	3.5	2.3	9.8

APPENDIX E

PRODUCT IDENTIFICATION

Gold Root Extract

INDIVIDUAL NECROPSY OBSERVATIONS



APPENDIX E

INDIVIDUAL NECROPSY OBSERVATIONS

<u>Animal Number</u>	<u>Tissue</u>	<u>Findings</u>
GROUP 1 - (0 ppm)		
<u>MALES</u>		
7957-7961	All tissues/organs	No gross abnormalities
<u>FEMALES</u>		
7962-7966	All tissues/organs	No gross abnormalities
GROUP 2 - (130 ppm)		
<u>MALES</u>		
7967-7971	All tissues/organs	No gross abnormalities
<u>FEMALES</u>		
7972-7976	All tissues/organs	No gross abnormalities
GROUP 3 - (1,300 ppm)		
<u>MALES</u>		
7977-7981	All tissues/organs	No gross abnormalities
<u>FEMALES</u>		
7982-7986	All tissues/organs	No gross abnormalities
GROUP 4 - (13,000 ppm)		
<u>MALES</u>		
7987-7991	All tissues/organs	No gross abnormalities
<u>FEMALES</u>		
7992-7996	All tissues/organs	No gross abnormalities

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APPENDIX F

PRODUCT IDENTIFICATION

Gold Root Extract

INDIVIDUAL FASTED TERMINAL BODY AND ORGAN WEIGHTS



APPENDIX F

INDIVIDUAL FASTED TERMINAL BODY AND ORGAN WEIGHTS (grams)

GROUP 1 - (0 ppm)

MALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7957	346.0	0.63	0.060	1.40	0.82	10.84	3.03	3.08
7958	331.0	0.60	0.055	1.33	0.91	10.52	3.54	3.02
7959	343.0	0.49	0.056	1.23	0.81	11.02	2.98	2.87
7960	347.0	0.72	0.073	1.46	0.92	10.86	3.55	2.74
7961	333.0	0.56	0.054	1.31	1.18	11.30	3.10	2.67
Average	340.0	0.60	0.060	1.35	0.93	10.91	3.24	2.88
SD	7.48	0.085	0.008	0.088	0.150	0.284	0.282	0.176

FEMALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7962	203.0	0.36	0.072	0.84	0.56	6.32	0.107	1.77
7963	201.0	0.36	0.082	0.97	0.52	6.37	0.109	1.79
7964	204.0	0.56	0.091	0.94	0.69	6.60	0.123	1.72
7965	236.0	0.59	0.108	1.07	0.89	8.37	0.102	1.99
7966	203.0	0.43	0.075	0.83	0.48	6.39	0.097	1.84
Average	209.4	0.46	0.086	0.93	0.63	6.81	0.108	1.82
SD	14.91	0.109	0.015	0.099	0.166	0.879	0.010	0.103

¹ Final fasted body weights were taken on Day 29.



APPENDIX F (cont.)

INDIVIDUAL FASTED TERMINAL BODY AND ORGAN WEIGHTS (grams)

GROUP 2 -(130 ppm)

MALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7967	354.0	0.68	0.059	1.49	0.82	10.74	2.89	2.93
7968	331.0	0.47	0.090	1.37	0.90	11.32	3.40	3.05
7969	341.0	0.54	0.065	1.40	0.86	11.12	3.09	3.12
7970	314.0	0.59	0.070	1.14	0.79	9.19	3.15	2.44
7971	358.0	0.77	0.076	1.22	0.74	10.65	3.17	2.78
Average	339.6	0.61	0.072	1.32	0.82	10.60	3.14	2.86
SD	17.87	0.118	0.012	0.142	0.062	0.836	0.183	0.270

FEMALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7972	243.0	0.84	0.081	1.00	0.73	8.30	0.088	2.18
7973	222.0	0.44	0.074	0.89	0.62	6.95	0.127	1.94
7974	214.0	0.62	0.100	0.95	0.70	7.48	0.113	1.96
7975	215.0	0.33	0.101	0.97	0.67	6.68	0.144	1.83
7976	208.0	0.49	0.091	0.97	0.56	7.40	0.104	1.89
Average	220.4	0.54	0.089	0.96	0.66	7.36	0.115	1.96
SD	13.58	0.196	0.012	0.041	0.067	0.618	0.021	0.133

¹ Final fasted body weights were taken on Day 29.

APPENDIX F (cont.)
INDIVIDUAL FASTED TERMINAL BODY AND ORGAN WEIGHTS (grams)
GROUP 3 - (1,300 ppm)
MALES

Animal No.	Body Weight¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7977	357.0	0.59	0.747 ²	1.44	0.75	10.97	3.60	3.22
7978	317.0	0.68	0.053	1.27	0.74	10.28	2.96	2.35
7979	362.0	0.72	0.071	1.20	0.77	11.03	3.64	2.82
7980	334.0	0.72	0.091	1.28	1.14	10.86	3.22	2.88
7981	333.0	0.62	0.061	1.25	0.79	11.24	2.88	2.85
Average	340.6	0.67	0.069	1.29	0.84	10.88	3.26	2.82
SD	18.61	0.059	0.016	0.090	0.170	0.361	0.352	0.310

FEMALES

Animal No.	Body Weight¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7982	209.0	0.47	0.075	0.93	0.47	6.84	0.135	1.93
7983	214.0	0.53	0.093	1.00	0.65	8.30	0.100	1.88
7984	214.0	0.62	0.071	0.99	0.57	7.20	0.131	1.82
7985	221.0	0.47	0.098	1.01	0.71	7.46	0.089	1.80
7986	212.0	0.64	0.100	0.92	0.55	7.02	0.106	1.93
Average	214.0	0.55	0.087	0.97	0.59	7.36	0.112	1.87
SD	4.42	0.081	0.014	0.042	0.093	0.571	0.020	0.061

¹ Final fasted body weights were taken on Day 29.

² Believed to be a recording error. Not used in the calculation of the average and standard deviation.



APPENDIX F (cont.)

INDIVIDUAL FASTED TERMINAL BODY AND ORGAN WEIGHTS (grams)

GROUP 4 - (13,000 ppm)

MALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7987	349.0	0.49	0.064	1.34	0.90	11.08	3.40	2.73
7988	345.0	0.86	0.060	1.16	0.71	10.34	3.48	2.66
7989	311.0	0.56	0.066	1.15	0.81	9.91	3.11	2.60
7990	341.0	0.63	0.069	1.28	1.03	11.05	3.34	3.03
7991	330.0	0.44	0.057	1.20	0.69	9.63	3.27	2.56
Average	335.2	0.60	0.063	1.23	0.83	10.40	3.32	2.72
SD	15.27	0.164	0.005	0.082	0.141	0.656	0.141	0.187

FEMALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7992	206.0	0.42	0.067	0.80	0.65	6.74	0.082	1.86
7993	231.0	0.49	0.084	1.06	0.52	8.49	0.110	2.09
7994	221.0	0.41	0.082	0.92	0.61	7.45	0.074	1.81
7995	196.0	0.59	0.075	0.81	0.47	5.84	0.100	1.53
7996	220.0	0.37	0.083	0.96	0.68	6.79	0.105	1.96
Average	214.8	0.46	0.078	0.91	0.59	7.06	0.094	1.85
SD	13.77	0.086	0.007	0.109	0.088	0.982	0.015	0.208

¹ Final fasted body weights were taken on Day 29.

3

APPENDIX G

PRODUCT IDENTIFICATION

Gold Root Extract

INDIVIDUAL ORGAN TO BODY WEIGHT RATIOS

APPENDIX G

INDIVIDUAL ORGAN TO BODY WEIGHT RATIOS ([organ weight/body weight] x 1000)

GROUP 1 - (0 ppm)

MALES

Animal No.	Body Weight¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7957	346.0	1.82	0.175	4.05	2.37	31.3	8.76	8.90
7958	331.0	1.81	0.165	4.02	2.75	31.8	10.69	9.12
7959	343.0	1.43	0.163	3.59	2.36	32.1	8.69	8.37
7960	347.0	2.07	0.211	4.21	2.65	31.3	10.23	7.90
7961	333.0	1.68	0.162	3.93	3.54	33.9	9.31	8.02
Average	340.0	1.76	0.175	3.96	2.74	32.1	9.54	8.46
SD	7.48	0.235	0.021	0.231	0.483	1.08	0.895	0.538

FEMALES

Animal No.	Body Weight¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7962	203.0	1.77	0.356	4.14	2.76	31.1	0.527	8.72
7963	201.0	1.79	0.405	4.83	2.59	31.7	0.542	8.91
7964	204.0	2.75	0.448	4.61	3.38	32.4	0.603	8.43
7965	236.0	2.50	0.458	4.53	3.77	35.5	0.432	8.43
7966	203.0	2.12	0.367	4.09	2.36	31.5	0.478	9.06
Average	209.4	2.19	0.407	4.44	2.97	32.4	0.516	8.71
SD	14.91	0.431	0.046	0.316	0.585	1.76	0.065	0.282

¹ Final fasted body weights were taken on Day 29.

APPENDIX G (cont.)
INDIVIDUAL ORGAN TO BODY WEIGHT RATIOS ([organ weight/body weight] x 1000)
GROUP 2 - (130 ppm)
MALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7967	354.0	1.92	0.167	4.21	2.32	30.3	8.16	8.28
7968	331.0	1.42	0.271	4.14	2.72	34.2	10.27	9.21
7969	341.0	1.58	0.190	4.11	2.52	32.6	9.06	9.15
7970	314.0	1.88	0.223	3.63	2.52	29.3	10.03	7.77
7971	358.0	2.15	0.212	3.41	2.07	29.7	8.85	7.77
Average	339.6	1.79	0.213	3.90	2.43	31.2	9.28	8.44
SD	17.87	0.289	0.039	0.357	0.247	2.10	0.869	0.713

FEMALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7972	243.0	3.46	0.333	4.12	3.00	34.2	0.362	8.97
7973	222.0	1.98	0.333	4.01	2.79	31.3	0.572	8.74
7974	214.0	2.90	0.467	4.44	3.27	35.0	0.528	9.16
7975	215.0	1.53	0.469	4.51	3.12	31.1	0.670	8.51
7976	208.0	2.36	0.439	4.66	2.69	35.6	0.500	9.09
Average	220.4	2.45	0.408	4.35	2.98	33.4	0.526	8.89
SD	13.58	0.755	0.070	0.276	0.235	2.09	0.112	0.266

¹ Final fasted body weights were taken on Day 29.

APPENDIX G (cont.)
INDIVIDUAL ORGAN TO BODY WEIGHT RATIOS ([organ weight/body weight] x 1000)
GROUP 3 - (1,300 ppm)
MALES

Animal No.	Body Weight¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7977	357.0	1.65	2.092 ²	4.03	2.10	30.7	10.08	9.02
7978	317.0	2.15	0.168	4.01	2.33	32.4	9.34	7.41
7979	362.0	1.99	0.196	3.31	2.13	30.5	10.06	7.79
7980	334.0	2.16	0.272	3.83	3.41	32.5	9.64	8.62
7981	333.0	1.86	0.182	3.75	2.37	33.8	8.65	8.56
Average	340.6	1.96	0.204	3.79	2.47	32.0	9.55	8.28
SD	18.61	0.211	0.047	0.289	0.541	1.4	0.593	0.658

FEMALES

Animal No.	Body Weight¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7982	209.0	2.25	0.361	4.45	2.25	32.7	0.646	9.23
7983	214.0	2.48	0.433	4.67	3.04	38.8	0.467	8.79
7984	214.0	2.90	0.329	4.63	2.66	33.6	0.612	8.50
7985	221.0	2.13	0.444	4.57	3.21	33.8	0.403	8.14
7986	212.0	3.02	0.473	4.34	2.59	33.1	0.500	9.10
Average	214.0	2.55	0.408	4.53	2.75	34.4	0.526	8.75
SD	4.42	0.392	0.060	0.136	0.381	2.5	0.101	0.444

¹ Final fasted body weights were taken on Day 29.

² Believed to be a recording error. Not used in the calculation of the average and standard deviation.

APPENDIX G (cont.)
INDIVIDUAL ORGAN TO BODY WEIGHT RATIOS ([organ weight/body weight] x 1000)
GROUP 4 - (13,000 ppm)
MALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Testes (paired)	Kidneys (paired)
7987	349.0	1.40	0.185	3.84	2.58	31.7	9.74	7.82
7988	345.0	2.49	0.174	3.36	2.06	30.0	10.09	7.71
7989	311.0	1.80	0.213	3.70	2.60	31.9	10.00	8.36
7990	341.0	1.85	0.201	3.75	3.02	32.4	9.79	8.89
7991	330.0	1.33	0.172	3.64	2.09	29.2	9.91	7.76
Average	335.2	1.78	0.189	3.66	2.47	31.0	9.91	8.11
SD	15.27	0.462	0.018	0.181	0.402	1.38	0.142	0.508

FEMALES

Animal No.	Body Weight ¹	Thymus	Adrenals (paired)	Heart	Spleen	Liver	Ovaries (paired)	Kidneys (paired)
7992	206.0	2.04	0.323	3.88	3.16	32.7	0.398	9.03
7993	231.0	2.12	0.361	4.59	2.25	36.8	0.476	9.05
7994	221.0	1.86	0.373	4.16	2.76	33.7	0.335	8.19
7995	196.0	3.01	0.383	4.13	2.41	29.8	0.510	7.81
7996	220.0	1.68	0.378	4.36	3.09	30.9	0.477	8.91
Average	214.8	2.14	0.364	4.23	2.73	32.8	0.439	8.60
SD	13.77	0.515	0.024	0.265	0.402	2.70	0.071	0.565

¹ Final fasted body weights were taken on Day 29.

APPENDIX H

PRODUCT IDENTIFICATION

Gold Root Extract

WEEKLY FOOD CONSUMPTION

APPENDIX H

WEEKLY FOOD CONSUMPTION (grams) – GROUP 1

MALES

Animal #	WEEK				Total
	1	2	3	4	
7957	194.5	195.0	190.3	191.6	771.4
7958	193.6	200.4	185.5	206.3	785.8
7959	191.0	208.2	192.2	206.3	797.7
7960	186.6	186.3	183.4	188.4	744.7
7961	201.3	214.1	208.0	219.6	843.0
Avg.	193.4	200.8	191.9	202.4	788.5
SD	5.4	10.9	9.7	12.6	36.3

FEMALES

Animal #	WEEK				Total
	1	2	3	4	
7962	129.6	119.5	139.6	140.0	528.7
7963	130.3	127.1	117.2	148.0	522.6
7964	128.0	136.1	139.2	144.2	547.5
7965	140.3	149.3	150.9	166.3	606.8
7966	130.3	133.4	128.8	140.4	532.9
Avg.	131.7	133.1	135.1	147.8	547.7
SD	4.9	11.1	12.7	10.8	34.3

APPENDIX H (cont.)
WEEKLY FOOD CONSUMPTION (grams) – GROUP 2
MALES

Animal #	WEEK				Total
	1	2	3	4	
7967	183.1	191.1	187.1	195.8	757.1
7968	176.2	182.1	175.5	182.5	716.3
7969	186.5	196.2	189.7	203.2	775.6
7970	170.2	176.9	174.6	171.7	693.4
7971	192.4	192.5	189.1	197.1	771.1
Avg.	181.7	187.8	183.2	190.1	742.7
SD	8.7	8.0	7.5	12.7	36.1

FEMALES

Animal #	WEEK				Total
	1	2	3	4	
7972	157.4	139.2	137.1	171.2	604.9
7973	136.2	155.7	138.1	143.6	573.6
7974	128.9	140.3	134.8	152.5	556.5
7975	136.0	142.9	134.9	135.8	549.6
7976	130.3	148.1	155.2	157.6	591.2
Avg.	137.8	145.2	140.0	152.1	575.2
SD	11.5	6.8	8.6	13.5	23.2



APPENDIX H (cont.)

WEEKLY FOOD CONSUMPTION (grams) – GROUP 3

MALES

Animal #	WEEK				Total
	1	2	3	4	
7977	163.5	221.2	201.1	193.3	779.1
7978	168.5	208.8	178.9	190.8	747.0
7979	163.6	210.0	191.5	209.5	774.6
7980	164.1	188.1	178.2	188.6	719.0
7981	180.2	197.0	190.3	198.4	765.9
Avg.	168.0	205.0	188.0	196.1	757.1
SD	7.1	12.8	9.6	8.3	24.6

FEMALES

Animal #	WEEK				Total
	1	2	3	4	
7982	127.7	143.8	113.9	132.6	518.0
7983	136.3	151.0	137.0	150.3	574.6
7984	139.9	141.4	127.3	139.6	548.2
7985	133.5	126.9	136.3	144.2	540.9
7986	132.5	144.1	120.3	149.7	546.6
Avg.	134.0	141.4	127.0	143.3	545.7
SD	4.5	8.9	10.0	7.4	20.2



APPENDIX H (cont.)

WEEKLY FOOD CONSUMPTION (grams) – GROUP 4

MALES

Animal #	WEEK				Total
	1	2	3	4	
7987	178.2	210.5	199.0	185.9	773.6
7988	187.5	192.6	186.1	188.7	754.9
7989	158.1	178.8	180.5	188.3	705.7
7990	188.5	194.8	198.3	197.5	779.1
7991	188.1	202.0	194.2	195.1	779.4
Avg.	180.1	195.7	191.6	191.1	758.5
SD	13.0	11.8	8.1	4.9	31.2

FEMALES

Animal #	WEEK				Total
	1	2	3	4	
7992	139.9	133.0	130.7	137.6	541.2
7993	151.5	146.9	142.1	154.3	594.8
7994	123.4	137.5	134.0	156.4	551.3
7995	132.4	123.6	124.3	126.6	506.9
7996	144.9	146.8	149.3	149.4	590.4
Avg.	138.4	137.6	136.1	144.9	556.9
SD	10.9	9.9	9.8	12.5	36.5

APPENDIX I

PRODUCT IDENTIFICATION

Gold Root Extract

HEMATOLOGY AND BLOOD CHEMISTRY

Huntingdon Life Sciences

Mettlers Road

East Millstone, NJ 08875



STUDY NO. 02-7571

CLINICAL PATHOLOGY SERVICES FOR A
28-DAY DIETARY TOXICITY STUDY IN RODENTS

Final Report

Submitted to: Product Safety Labs
725 Cranberry Road
East Brunswick, New Jersey 08816-3206

Attn: George E. Moore

Date: 8 May, 2002

Huntingdon Life Sciences

02-7571

Final Report

SIGNATURE PAGE

SCIENTIST

The following Scientist was responsible for the overall conduct of this study. Departmental supervisory personnel are listed on the personnel page of this report (Appendix D).

Barbara A. Litzenberger

Barbara A. Litzenberger, B.S., M.T. (ASCP)
Principal Investigator

8 May 02

Date

Huntingdon Life Sciences

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1. MATERIALS AND METHODS

1.1. STUDY MANAGEMENT

1.1.1. SUBCONTRACTOR'S SPONSOR

Product Safety Labs
725 Cranberry Road
East Brunswick, New Jersey 08816-3206

1.1.2. STUDY DIRECTOR

George E. Moore

1.1.3. SUBCONTRACTOR

Huntingdon Life Sciences
P.O. Box 2360
Mettlers Road
East Millstone, New Jersey 08875-2360

1.1.4. PRINCIPAL INVESTIGATOR

Barbara A. Litzenberger, B.S., M.T. (ASCP)

1.2. CLINICAL PATHOLOGY

Clinical pathology procedures and parameters are based on those recommended in published guidelines (Joint Scientific Committee, 1996).

40 samples were received on 17 January 2002 and analyzed as follows:

1.2.1. HEMATOLOGY

Blood samples were analyzed as follows:

ADVIA 120 Hematology Analyzer, Bayer Corporation

Hemoglobin concentration
Hematocrit
Erythrocyte count
Platelet count
Total leukocyte count
Differential leukocyte count¹

¹When questionable values were obtained, manual differential leukocyte counts (Henry, 1991) and absolute value calculations were performed for verification.

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1.2.2. COAGULATION

Blood samples were analyzed as follows:

**Mechanical clot detection system, STA Compact[®],
Diagnostica Stago Products**

Prothrombin time
Activated partial thromboplastin time

1.2.3. CLINICAL CHEMISTRY

Blood samples were analyzed as follows:

Hitachi 717, Roche Corporation Automatic Analyzer

Aspartate aminotransferase (*Kinetic - Modified IFCC Technique*)
Alanine aminotransferase (*Kinetic - Modified IFCC Technique*)
Alkaline phosphatase (*Kinetic - Modified AMP Buffer*)
Blood urea nitrogen (*Kinetic - Modified Urease*)
Creatinine (*Kinetic - Modified Jaffe Method*)
Glucose (*Hexokinase Method*)
Cholesterol (*Enzymatic - Modified Trinder Method*)
Total protein (*Biuret Technique*)
Albumin (*Bromocresol Green Method*)
Total bilirubin (*Modified Wahlefield et al.*)
Sodium (*Ion Selective Electrode*)
Potassium (*Ion Selective Electrode*)
Chloride (*Ion Selective Electrode*)
Calcium (*Cresolphthalein Complexone Method*)
Inorganic phosphorus (*Phosphomolybdate - UV Method*)
Magnesium (*Xylylidyl Blue Method*)
Gamma-glutamyl transpeptidase (*Kinetic - Modified Persijn and Vander Silk Method*)

Other

Globulin (*calculated value; total protein - albumin*)

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1.3. DATA STORAGE

All remaining serum from clinical chemistry studies will be maintained at the Subcontract Laboratory for 6 months after completion of analysis and then discarded. The original final subcontractor report will be maintained in the Archives of the Subcontract Laboratory upon completion of the study. The Sponsor will determine the final disposition of these materials.

1.4. REGULATORY REFERENCES

1.4.1. GOOD LABORATORY PRACTICES

This study was exempt from Good Laboratory Practice (GLP) Standards. However, sample analysis was performed according to the Testing Facility's Standard Operating Procedures and in the spirit of GLP standards in regards to laboratory procedures (e.g. data collection, recording, etc.).

1.5. PROTOCOL DEVIATIONS

No protocol deviations occurred during this study.

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REFERENCES

Henry, John Bernard, M.D. 1991. *Clinical Diagnosis and Management by Laboratory Methods*. 18th edition. Philadelphia: W.B. Saunders Co.

Joint Scientific Committee for International Harmonization of Clinical Pathology Testing, 1996. Harmonization of Animal Clinical Testing in Toxicity and Safety Studies. Fundamentals of Applied Toxicology ; 29:198-201.

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	General Preface	
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General Notes

Individual animal data values presented in this report may be rounded. Unrounded individual animal data values are used to calculate the reported mean and standard deviation values. Therefore, use of the reported individual values to reproduce means, standard deviations and/or to perform any subsequent calculations may produce minor discrepancies between the calculated values and those presented in this report.

Key to Abbreviations

M = Male

F = Female

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	Individual Hematology Values Preface	Appendix A
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Abbreviation	Parameter	Reporting Units
HGB	Hemoglobin Concentration	g/dL
HCT	Hematocrit	percent
RBC	Erythrocyte Count	$10^6/\mu\text{L}$
PLT	Platelet Count	$10^3/\mu\text{L}$
WBC	Total Leukocyte Count	$10^3/\mu\text{L}$
ANEU	Absolute Neutrophils	$10^3/\mu\text{L}$
ALYM	Absolute Lymphocytes	$10^3/\mu\text{L}$
AMONO	Absolute Monocytes	$10^3/\mu\text{L}$
AEOS	Absolute Eosinophils	$10^3/\mu\text{L}$
ABASO	Absolute Basophils	$10^3/\mu\text{L}$
ALUC	Absolute Large Unstained Cells	$10^3/\mu\text{L}$
Abs. Atyp Lymph	Absolute Atypical Lymphocytes	$10^3/\mu\text{L}^*$

* Only reported when observed

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Appendix A

Individual Hematology Values - Termination

Group	Number	Animal		PLT	WBC	ANEU	ALYM	AMONO	AEOS
		HGB	HCT						
		g/dL	%	x10^6/uL	x10^3/uL	x10^3/uL	x10^3/uL	x10^3/uL	x10^3/uL
1M	7957	17.0	50.4	9.63	1048	12.58	0.53	11.53	0.23
	7958	17.8	51.0	9.51	904	11.73	0.73	10.39	0.36
	7959	17.1	49.8	9.01	1045	9.79	0.53	8.70	0.30
	7960	16.6	49.2	8.78	954	10.95	0.98	9.34	0.27
	7961	16.4	48.4	8.56	1063	11.02	0.73	9.79	0.28
	Mean	17.0	49.8	9.10	1003	11.21	0.70	9.95	0.29
	SD	0.54	1.01	0.461	70.0	1.033	0.186	1.078	0.048
	n	5	5	5	5	5	5	5	5
2M	7967	16.5	48.4	9.20	898	11.22	1.26	9.14	0.25
	7968	16.4	47.5	8.59	1112	9.06	0.68	7.90	0.28
	7969	14.3	41.3	7.65	730	8.11	1.83	5.56	0.34
	7970	17.0	49.2	9.24	669	7.69	1.00	6.31	0.10
	7971	16.5	47.5	8.95	952	6.42	0.49	5.61	0.17
	Mean	16.1	46.8	8.73	872	8.50	1.05	6.90	0.23
	SD	1.05	3.14	0.655	177.5	1.792	0.526	1.567	0.094
	n	5	5	5	5	5	5	5	5

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Appendix A
Individual Hematology Values - Termination

Group	Animal Number	x10^3/uL		
		ABASO	ALUC	
1M	7957	0.07	0.11	
	7958	0.07	0.06	
	7959	0.05	0.06	
	7960	0.04	0.07	
	7961	0.05	0.05	
	Mean	0.06	0.07	
	SD	0.013	0.023	
	n	5	5	
2M	7967	0.05	0.07	
	7968	0.06	0.04	
	7969	0.03	0.05	
	7970	0.04	0.03	
	7971	0.03	0.04	
	Mean	0.04	0.05	
	SD	0.013	0.015	
	n	5	5	

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Appendix A

Individual Hematology Values - Termination

Group	Number	Animal								
		HGB	HCT	RBC	PLT	WBC	ANEU	ALYM	AMONO	AEOS
g/dL % x10^6/uL x10^3/uL x10^3/uL x10^3/uL x10^3/uL x10^3/uL x10^3/uL x10^3/uL										
3M	7977	17.0	50.5	9.13	695	7.53	0.53	6.40	0.23	0.15
	7978	17.5	51.4	9.44	433	7.47	0.96	5.43	0.26	0.77
	7979	16.4	49.3	9.52	388	8.64	0.43	7.86	0.09	0.00
	7980	16.3	48.0	8.87	1047	6.80	0.75	5.72	0.16	0.12
	7981	16.9	50.6	9.21	1026	8.38	0.63	7.44	0.14	0.09
	Mean	16.8	50.0	9.23	718	7.76	0.66	6.57	0.18	0.23
	SD	0.49	1.33	0.259	313.8	0.745	0.205	1.057	0.069	0.309
	n	5	5	5	5	5	5	5	5	5
4M	7987	17.1	50.4	9.14	1157	5.04	0.42	4.49	0.07	0.04
	7988	17.2	50.2	9.58	1049	6.86	0.72	5.82	0.15	0.10
	7989	16.9	50.0	9.46	1326	9.31	0.90	7.86	0.32	0.13
	7990	17.4	50.5	9.36	1027	9.60	0.64	8.55	0.21	0.13
	7991	17.0	49.9	9.14	979	7.80	0.95	6.47	0.17	0.15
	Mean	17.1	50.2	9.34	1108	7.72	0.73	6.64	0.18	0.11
	SD	0.19	0.25	0.195	138.4	1.870	0.213	1.617	0.092	0.043
	n	5	5	5	5	5	5	5	5	5

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Appendix A

Individual Hematology Values - Termination

Group	Number	Animal		
		ABASO	ALUC	Abs. Atyp Lymph
		x10 ³ /uL	x10 ³ /uL	x10 ³ /uL
3M	7977	0.00	0.00	0.23
	7978	0.03	0.03	
	7979	0.00	0.00	0.26
	7980	0.03	0.04	
	7981	0.05	0.04	
	Mean	0.02	0.02	
	SD	0.022	0.020	
	n	5	5	
4M	7987	0.01	0.02	
	7988	0.03	0.04	
	7989	0.05	0.04	
	7990	0.02	0.05	
	7991	0.02	0.03	
	Mean	0.03	0.04	
	SD	0.015	0.011	
	n	5	5	

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Appendix A

Individual Hematology Values - Termination

Group	Number	Animal								
		g/dL	%	x10^6/uL	x10^3/uL	x10^3/uL	x10^3/uL	x10^3/uL	x10^3/uL	x10^3/uL
1F	7962	15.3	43.9	8.13	1314	4.77	0.30	4.27	0.11	0.05
	7963	15.8	46.1	8.45	1156	5.58	0.52	4.76	0.17	0.09
	7964	16.6	47.4	8.70	1073	9.07	0.71	7.96	0.16	0.18
	7965	16.4	47.2	8.62	1353	7.90	0.59	6.95	0.16	0.10
	7966	14.4	40.1	7.65	1167	6.21	1.18	4.67	0.20	0.12
	Mean	15.7	44.9	8.31	1213	6.71	0.66	5.72	0.16	0.11
	SD	0.89	3.04	0.429	117.0	1.752	0.327	1.632	0.032	0.048
	n	5	5	5	5	5	5	5	5	5
2F	7972	15.4	44.3	8.14	1204	8.21	0.64	7.16	0.15	0.17
	7973	16.6	48.2	8.85	1177	5.53	0.28	4.95	0.15	0.10
	7974	16.0	45.3	8.58	1126	5.57	0.69	4.71	0.05	0.07
	7975	12.7	36.3	6.59	937	4.16	0.50	3.37	0.11	0.14
	7976	16.7	48.0	8.70	504	4.06	0.45	3.37	0.12	0.00
	Mean	15.5	44.4	8.17	990	5.51	0.51	4.71	0.12	0.10
	SD	1.64	4.84	0.923	290.8	1.675	0.163	1.553	0.041	0.066
	n	5	5	5	5	5	5	5	5	5

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Appendix A

Individual Hematology Values - Termination

Group	Animal Number	ABASO	ALUC	Abs.
				Atyp Lymph
		x10 ³ /uL	x10 ³ /uL	x10 ³ /uL
1F	7962	0.01	0.03	
	7963	0.02	0.02	
	7964	0.02	0.04	
	7965	0.04	0.06	
	7966	0.02	0.02	
	Mean	0.02	0.03	
	SD	0.011	0.017	
	n	5	5	
2F	7972	0.02	0.07	
	7973	0.02	0.02	
	7974	0.03	0.03	
	7975	0.01	0.02	
	7976	0.00	0.00	0.12
	Mean	0.02	0.03	
	SD	0.011	0.026	
	n	5	5	

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Appendix A

Individual Hematology Values - Termination

Group	Number	Animal		PLT	WBC	ANEU	ALYM	AMONO	AEOS
		HGB	HCT						
		g/dL	%	x10^6/uL	x10^3/uL	x10^3/uL	x10^3/uL	x10^3/uL	x10^3/uL
3F	7982	16.3	45.8	8.63	1257	5.24	0.52	4.54	0.08
	7983	16.6	48.9	8.84	431	4.42	0.27	3.89	0.04
	7984	16.2	46.5	8.73	1380	5.59	0.34	5.05	0.07
	7985	15.7	44.8	8.13	1064	5.89	0.43	5.23	0.11
	7986	16.9	47.4	9.02	1324	6.28	0.58	5.38	0.08
	Mean	16.3	46.7	8.67	1091	5.48	0.43	4.82	0.08
	SD	0.45	1.56	0.335	387.8	0.707	0.127	0.608	0.025
	n	5	5	5	5	5	5	5	5
4F	7992	16.7	48.7	8.89	1057	6.75	0.38	5.87	0.07
	7993	15.9	46.1	8.46	326	5.72	0.74	4.60	0.18
	7994	15.6	45.9	8.56	1068	5.52	0.47	4.88	0.07
	7995	17.0	50.2	9.03	536	3.65	0.15	3.32	0.04
	7996	16.2	46.4	8.82	1295	4.70	0.29	4.26	0.05
	Mean	16.3	47.5	8.75	856	5.27	0.41	4.59	0.08
	SD	0.57	1.90	0.236	406.6	1.162	0.221	0.928	0.056
	n	5	5	5	5	5	5	5	5

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Appendix A

Individual Hematology Values - Termination

Group	Number	Animal				
		ABASO	ALUC	Abs.		
				Atyp		
				Lymph		
$\times 10^3/\mu\text{L}$						
$\times 10^3/\mu\text{L}$						
$\times 10^3/\mu\text{L}$						
3F						
7982 0.01 0.03						
7983 0.00 0.00 0.09						
7984 0.01 0.02						
7985 0.02 0.03						
7986 0.03 0.03						
Mean 0.01 0.02						
SD 0.011 0.013						
n 5 5						
4F						
7992 0.02 0.03						
7993 0.02 0.02						
7994 0.01 0.01						
7995 0.00 0.00 0.07						
7996 0.02 0.03						
Mean 0.01 0.02						
SD 0.009 0.013						
n 5 5						

Huntingdon Life Sciences

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	Individual Coagulation Values Preface	Appendix B
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Abbreviation	Parameter	Reporting Units
PT	Prothrombin Time	seconds
APTT	Activated Partial Thromboplastin Time	seconds

Key to Other Abbreviations

- CS = Clotted specimen
NV = Non-valid; result unobtainable

Huntingdon Life Sciences Study No.: 02-7571

Appendix B

Individual Coagulation Values - Termination

Group	Number	Animal	
		PT	APTT
		Seconds	Seconds
1M	7957	12.4	18.9
	7958	12.4	21.2
	7959	12.5	17.6
	7960	13.2	21.6
	7961	12.5	20.1
	Mean	12.6	19.9
	SD	0.34	1.65
	n	5	5
2M	7967	12.2	18.8
	7968	12.4	18.5
	7969	12.1	21.5
	7970	12.5	18.3
	7971	11.8	18.0
	Mean	12.2	19.0
	SD	0.27	1.42
	n	5	5

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Appendix B

Individual Coagulation Values - Termination

Group	Number	Animal	
		PT	APTT
		Seconds	Seconds
3M	7977	12.0	19.0
	7978	12.7	18.8
	7979	12.2	17.4
	7980	11.2	19.0
	7981	11.7	19.5
	Mean	12.0	18.7
	SD	0.56	0.79
	n	5	5
4M	7987	13.5	21.3
	7988	12.7	20.4
	7989	11.9	17.6
	7990	12.0	21.0
	7991	12.9	22.9
	Mean	12.6	20.6
	SD	0.66	1.93
	n	5	5

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Appendix B

Individual Coagulation Values - Termination

Group	Animal Number	PT		APTT
		Seconds	Seconds	
1F	7962	11.8	16.9	
	7963	11.7	16.9	
	7964	11.9	15.8	
	7965	11.6	14.7	
	7966	CS	CS	
	Mean	11.8	16.1	
	SD	0.13	1.05	
	n	4	4	
2F	7972	11.7	16.2	
	7973	12.1	16.7	
	7974	11.6	16.7	
	7975	11.2	16.3	
	7976	11.5	17.6	
	Mean	11.6	16.7	
	SD	0.33	0.55	
	n	5	5	

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Appendix B

Individual Coagulation Values - Termination

Group	Number	Animal	
		PT	APTT
		Seconds	Seconds
3F	7982	12.1	NV
	7983	11.4	16.2
	7984	11.3	14.0
	7985	11.5	15.4
	7986	11.5	15.4
	Mean	11.6	15.3
	SD	0.31	0.91
	n	5	4
4F	7992	11.7	18.6
	7993	13.7	15.7
	7994	12.4	22.2
	7995	CS	CS
	7996	11.9	16.4
	Mean	12.4	18.2
	SD	0.90	2.92
	n	4	4

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	Individual Clinical Chemistry Values Preface	Appendix C
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Abbreviation	Parameter	Reporting Units
AST	Aspartate Aminotransferase	U/L
ALT	Alanine Aminotransferase	U/L
ALKP	Alkaline Phosphatase	U/L
BUN	Blood Urea Nitrogen	mg/dL
CREAT	Creatinine	mg/dL
GLU	Fasting Glucose	mg/dL
CHOL	Cholesterol (Enzymatic)	mg/dL
TP	Total Protein	g/dL
ALB	Albumin	g/dL
Glob	Globulin (calculated)	g/dL
TBILI	Total Bilirubin	mg/dL
Na ⁺	Sodium	mEq/L
K ⁺	Potassium	mEq/L
Cl ⁻	Chloride	mEq/L
Ca ⁺⁺	Calcium	mg/dL
PHOS	Inorganic Phosphorus	mg/dL
Mg ⁺⁺	Magnesium	mg/dL
GGT	Gamma-Glutamyl Transferase	U/L

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Appendix C

Individual Clinical Chemistry Values - Termination

Group	Number	Animal									
		AST	ALT	ALKP	BUN	CREAT	GLU	CHOL	TP	ALB	
		U/L	U/L	U/L	mg/dL	mg/dL	mg/dL	g/dL	g/dL		
1M	7957	139	39	124	13.1	0.2	99	80	6.4	4.1	
	7958	182	46	134	12.9	0.2	113	114	6.3	3.7	
	7959	139	41	159	14.3	0.3	136	80	6.3	4.0	
	7960	204	48	179	12.2	0.3	105	79	6.4	4.2	
	7961	166	47	202	17.3	0.3	117	62	6.0	3.7	
	Mean	166	44	160	14.0	0.3	114	83	6.3	3.9	
	SD	28.1	4.0	32.0	2.01	0.05	14.1	18.9	0.16	0.23	
	n	5	5	5	5	5	5	5	5	5	
2M	7967	160	48	156	11.6	0.3	80	83	6.4	4.2	
	7968	149	47	166	12.4	0.3	105	74	6.2	4.0	
	7969	236	50	116	16.1	0.4	139	62	6.1	3.8	
	7970	228	47	143	15.9	0.3	127	57	6.5	4.2	
	7971	188	40	129	13.0	0.3	99	91	6.1	4.1	
	Mean	192	46	142	13.8	0.3	110	73	6.3	4.1	
	SD	39.1	3.8	20.1	2.07	0.04	23.3	14.2	0.18	0.17	
	n	5	5	5	5	5	5	5	5	5	

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Individual Clinical Chemistry Values - Termination

Group	Animal Number	Animal								
		Glob	TBILI	Na+	K+	Cl-	Ca++	PHOS	Mg++	GGT
		g/dL	mg/dL	mEq/L	mEq/L	mEq/L	mg/dL	mEq/L	U/L	
1M	7957	2.3	0.06	148	4.8	103	10.5	7.1	2.00	0
	7958	2.6	0.04	147	4.9	103	10.1	7.5	1.72	0
	7959	2.3	0.11	147	4.9	103	10.3	7.3	1.87	0
	7960	2.2	0.08	148	5.0	105	10.5	6.6	1.75	0
	7961	2.3	0.04	147	4.7	105	10.1	6.9	1.76	0
	Mean	2.3	0.07	147	4.9	104	10.3	7.1	1.82	0
2M	SD	0.15	0.030	0.5	0.11	1.1	0.20	0.35	0.116	0.0
	n	5	5	5	5	5	5	5	5	5
	7967	2.2	0.08	149	4.5	105	10.3	7.9	1.87	0
	7968	2.2	0.06	147	5.1	105	10.2	6.8	1.68	0
	7969	2.3	0.05	148	4.7	106	9.8	7.5	2.13	0
	7970	2.3	0.08	149	5.2	106	10.3	6.6	1.79	0
2M	7971	2.0	0.08	147	5.1	105	10.2	7.0	1.76	0
	Mean	2.2	0.07	148	4.9	105	10.2	7.2	1.85	0
	SD	0.12	0.014	1.0	0.30	0.5	0.21	0.53	0.173	0.0
	n	5	5	5	5	5	5	5	5	5

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Individual Clinical Chemistry Values - Termination

Group	Number	Animal								
		AST	ALT	ALKP	BUN	CREAT	GLU	CHOL	TP	ALB
		U/L	U/L	U/L	mg/dL	mg/dL	mg/dL	g/dL	g/dL	
3M	7977	220	59	166	11.8	0.3	108	76	6.5	4.3
	7978	188	62	255	16.6	0.4	88	75	6.4	3.9
	7979	189	41	189	11.1	0.3	106	67	6.4	4.3
	7980	204	36	150	16.0	0.2	92	69	6.3	3.9
	7981	161	51	130	11.2	0.2	100	82	6.6	4.2
	Mean	192	50	178	13.3	0.3	99	74	6.4	4.1
	SD	21.9	11.2	48.2	2.72	0.08	8.7	6.0	0.11	0.20
	n	5	5	5	5	5	5	5	5	5
4M	7987	164	55	222	13.9	0.3	108	61	6.7	4.3
	7988	149	48	148	12.5	0.3	104	74	6.6	4.4
	7989	153	41	181	13.7	0.2	94	60	6.8	4.4
	7990	136	38	171	15.2	0.2	100	92	6.7	4.1
	7991	146	47	267	10.6	0.3	98	68	6.6	4.4
	Mean	150	46	198	13.2	0.3	101	71	6.7	4.3
	SD	10.2	6.6	47.0	1.73	0.05	5.4	13.0	0.08	0.13
	n	5	5	5	5	5	5	5	5	5

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Individual Clinical Chemistry Values - Termination

Group	Number	Animal									
		Glob	TBIL	Na+	K+	Cl-	Ca++	PHOS	Mg++	GGT	
		g/dL	mg/dL	mEq/L	mEq/L	mEq/L	mg/dL	mg/dL	mEq/L	U/L	
3M	7977	2.2	0.07	150	4.9	108	10.6	7.4	1.82	0	
	7978	2.5	0.06	148	4.8	104	9.8	7.4	1.88	0	
	7979	2.1	0.09	148	5.1	105	10.6	7.6	1.90	0	
	7980	2.4	0.06	148	5.3	107	10.3	7.0	1.74	0	
	7981	2.4	0.03	148	5.3	106	10.8	7.0	1.77	0	
	Mean	2.3	0.06	148	5.1	106	10.4	7.3	1.82	0	
	SD	0.16	0.022	0.9	0.23	1.6	0.39	0.27	0.069	0.0	
	n	5	5	5	5	5	5	5	5	5	
4M	7987	2.4	0.10	151	5.1	108	9.8	7.1	1.69	0	
	7988	2.2	0.08	149	5.4	107	10.4	7.6	1.80	0	
	7989	2.4	0.07	149	5.2	106	11.0	7.6	1.83	0	
	7990	2.6	0.04	151	5.2	106	10.5	8.0	1.79	0	
	7991	2.2	0.09	150	4.9	108	10.7	8.6	1.87	0	
	Mean	2.4	0.08	150	5.2	107	10.5	7.8	1.80	0	
	SD	0.17	0.023	1.0	0.18	1.0	0.44	0.56	0.067	0.0	
	n	5	5	5	5	5	5	5	5	5	

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Individual Clinical Chemistry Values - Termination

Group	Number	Animal								
		AST	ALT	ALKP	BUN	CREAT	GLU	CHOL	TP	ALB
		U/L	U/L	U/L	mg/dL	mg/dL	mg/dL	g/dL	g/dL	
1F	7962	165	39	147	12.4	0.2	98	81	6.6	4.5
	7963	154	53	112	13.5	0.2	90	61	6.1	4.4
	7964	184	43	122	16.8	0.3	104	63	6.1	4.1
	7965	181	37	155	16.4	0.3	113	83	6.3	4.2
	7966	156	34	100	12.8	0.2	95	67	6.1	4.3
	Mean	168	41	127	14.4	0.2	100	71	6.2	4.3
	SD	13.9	7.4	23.3	2.07	0.05	8.9	10.3	0.22	0.16
	n	5	5	5	5	5	5	5	5	5
2F	7972	171	37	139	13.8	0.2	114	86	6.0	4.0
	7973	156	39	148	16.1	0.3	82	62	6.2	4.1
	7974	192	30	154	15.7	0.3	102	66	6.2	4.5
	7975	124	35	113	17.4	0.3	87	61	6.3	4.3
	7976	141	29	87	15.3	0.2	113	72	6.1	4.1
	Mean	157	34	128	15.7	0.3	100	69	6.2	4.2
	SD	26.3	4.4	27.9	1.30	0.05	14.7	10.2	0.11	0.20
	n	5	5	5	5	5	5	5	5	5



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Individual Clinical Chemistry Values - Termination

Group	Number	Animal									
		Glob	TBIL	Na+	K+	Cl-	Ca++	PHOS	Mg++	GGT	
		g/dL	mg/dL	mEq/L	mEq/L	mEq/L	mg/dL	mg/dL	mEq/L	U/L	
1F	7962	2.1	0.06	147	5.1	107	10.2	6.1	1.98	0	
	7963	1.7	0.14	145	4.7	104	10.0	6.2	1.89	0	
	7964	2.0	0.11	146	5.3	108	10.2	6.4	1.95	0	
	7965	2.1	0.08	145	4.7	104	10.5	7.1	2.01	0	
	7966	1.8	0.09	145	4.8	104	10.0	5.6	2.03	0	
	Mean	1.9	0.10	146	4.9	105	10.2	6.3	1.97	0	
	SD	0.18	0.030	0.9	0.27	1.9	0.20	0.54	0.055	0.0	
	n	5	5	5	5	5	5	5	5	5	
2F	7972	2.0	0.07	145	5.1	104	10.2	6.9	2.06	0	
	7973	2.1	0.12	146	4.7	106	10.5	7.0	2.00	0	
	7974	1.7	0.09	148	5.0	108	10.3	6.0	2.02	0	
	7975	2.0	0.08	147	4.4	106	10.1	7.2	1.90	0	
	7976	2.0	0.08	146	4.5	106	10.5	6.9	1.90	0	
	Mean	2.0	0.09	146	4.7	106	10.3	6.8	1.98	0	
	SD	0.15	0.019	1.1	0.30	1.4	0.18	0.46	0.073	0.0	
	n	5	5	5	5	5	5	5	5	5	

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Individual Clinical Chemistry Values - Termination

Group	Number	Animal									
		AST	ALT	ALKP	BUN	CREAT	GLU	CHOL	TP	ALB	
		U/L	U/L	U/L	mg/dL	mg/dL	mg/dL	g/dL	g/dL	g/dL	
3F	7982	150	35	92	14.5	0.3	81	87	6.2	4.2	
	7983	183	34	93	16.2	0.3	93	81	6.2	4.3	
	7984	227	32	86	15.4	0.2	106	93	6.4	4.3	
	7985	184	32	146	14.8	0.3	106	98	6.4	4.3	
	7986	174	35	120	14.7	0.3	117	78	6.5	4.5	
	Mean	184	34	107	15.1	0.3	101	87	6.3	4.3	
	SD	27.9	1.5	25.3	0.69	0.04	13.9	8.3	0.13	0.11	
	n	5	5	5	5	5	5	5	5	5	
4F	7992	200	39	79	16.3	0.3	92	58	6.4	4.3	
	7993	161	39	103	14.2	0.3	85	48	6.1	4.2	
	7994	130	35	118	12.6	0.3	92	83	6.1	4.2	
	7995	181	37	82	20.3	0.4	89	69	6.1	4.2	
	7996	154	27	109	16.3	0.2	104	62	6.2	4.5	
	Mean	165	35	98	15.9	0.3	92	64	6.2	4.3	
	SD	26.7	5.0	17.0	2.89	0.07	7.1	13.1	0.13	0.13	
	n	5	5	5	5	5	5	5	5	5	

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Individual Clinical Chemistry Values - Termination

Group	Number	Animal									
		Glob	TBIL	Na+	K+	Cl-	Ca++	PHOS	Mg++	GGT	
		g/dL	mg/dL	mEq/L	mEq/L	mEq/L	mg/dL	mg/dL	mEq/L	U/L	
3F	7982	2.0	0.08	146	4.6	105	10.4	6.4	2.04	1	
	7983	1.9	0.12	144	5.1	107	10.9	8.3	2.17	0	
	7984	2.1	0.09	146	5.1	104	10.6	7.6	2.17	0	
	7985	2.1	0.10	147	5.1	105	10.7	7.8	1.92	0	
	7986	2.0	0.13	147	5.4	106	10.4	7.4	2.05	0	
	Mean	2.0	0.10	146	5.1	105	10.6	7.5	2.07	0	
4F	SD	0.08	0.021	1.2	0.29	1.1	0.21	0.70	0.105	0.4	
	n	5	5	5	5	5	5	5	5	5	
	7992	2.1	0.11	151	5.3	110	10.3	7.5	1.90	0	
	7993	1.9	0.08	148	4.8	108	10.1	7.1	1.96	0	
	7994	1.9	0.08	146	4.9	105	10.4	6.9	2.03	1	
	7995	1.9	0.09	151	5.0	111	10.5	7.1	2.07	0	
	7996	1.7	0.13	150	4.6	112	10.3	6.4	1.95	0	
	Mean	1.9	0.10	149	4.9	109	10.3	7.0	1.98	0	
	SD	0.14	0.022	2.2	0.26	2.8	0.15	0.40	0.068	0.4	
	n	5	5	5	5	5	5	5	5	5	

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	Subcontractor Personnel	Appendix D
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TITLE/DEPARTMENT	NAME/DEGREE
PRINCIPAL INVESTIGATOR	Barbara A. Litzenberger, B.S., M.T. (ASCP)
PROJECT MANAGER	Lisa Spall, B.S.
STUDY MONITOR	Doris J. Bowden, B.S.

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	Report Amendments	Appendix E
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There are no amendments for this report at this time.



APPENDIX I (cont.)

Attachment I

Historical Control Data for Selected Hematology and Clinical Chemistry Parameters¹

	Males					Females				
	Mean	SD	Min	Max	N	Mean	SD	Min	Max	N
Hematology										
Lymphocytes (x 10 ³ /ul)	11.0	3.6	4.3	19.6	36	8.5	2.8	3.7	13	10
White blood cell count (x 10 ³ /ul)	12.6	3.7	6.4	21.7	46	10.0	3.3	4.2	15.9	10
Monocytes (x 10 ³ /ul)	0.22	0.09	0.09	0.50	36	0.13	0.06	0.04	0.24	10
Basophils (x 10 ³ /ul)	0.13	0.09	0.03	0.53	36	0.07	0.05	0.00	0.15	10
Large unstained cells (x 10 ³ /ul)	0.09	0.18	0.02	1.13	36	0.04	0.02	0.00	0.07	10
Hematocrit (%)	47.5	3.4	33.1	53.5	46	46.4	1.7	43.2	50.6	40
Clinical Chemistry										
Sodium (mEq/L)	146	3	140	155	161	146	3	140	155	131
Chloride (mEq/L)	102	3	94	112	161	102	3	94	112	131
Calcium (mg/dL)	10.4	0.5	9.2	12.2	161	10.3	0.4	9.2	11.5	131
Phosphorus (mg/dL)	10.6	1.1	8.3	14.1	161	10.5	0.9	8.3	12.6	131
Total protein (g/dL)	6.1	0.4	5.4	7.0	161	6.1	0.4	5.4	7.0	131
Albumin (g/dL)	4.3	0.2	3.5	5.3	161	4.3	0.2	3.5	4.9	131

SD – Standard deviation

Min – Minimum; Max – Maximum

N – Number tested

¹ Recent Huntingdon Life Sciences data for male and female rats of an age and strain comparable to rats used in PSL study #11326 (Huntingdon Life Sciences study no. 02-7571).